Analysis of a "Simple" Medical Device

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MEDICAL DEVICES ARE DESIGNED TO improve the health of an individual. Advances in the technology of medical devices may enable patients to take an active role in maintaining their own health. One example is the hand-held, battery-operated meter that patients with diabetes can use to check their blood glucose levels. Through self-monitoring, diabetes patients can determine their blood sugar levels and adjust diet, insulin, or exercise to effectively manage their diabetes.

The advent of self-care, unfortunately, has some negative consequences as well. The patient must take primary responsibility for monitoring blood glucose levels without assistance from a health care professional. As a result, there may be an increase in the occurrence of errors in the use of blood glucose meters (see Laux, 1994, for monitoring difficulties when meters are unavailable). These errors can have serious consequences for the short- and long-term health of the individual, particularly because treatment is often determined from glucose level readings. Diabetes can lead to many complications if not properly treated, including high blood pressure, heart or kidney disease, vision problems or blindness, complications in pregnancy, and death.

Blood glucose meters represent a class of home health care technologies in which the tasks are sequential in nature – that is, each step is reliant on the success of the previous step. The system also provides very little feedback about the accuracy of performance, and the consequences of errors are high. Other devices in this class would include blood pressure monitors, heart rate monitors, oxygen tanks, and infusion pumps. In this article, we demonstrate how human factors/ergonomics tools can be applied to medical devices in general, and blood glucose meters in particular. We focus on blood glucose meters because of their widespread use and availability, but our approach and findings can be generalized to other home health care devices.

Definitely Not "As Easy as 1, 2, 3"

"It's as easy as 1, 2, 3" begins the videotape that accompanies a commonly used blood glucose meter. "Simply set up the meter, check the system, and test your blood." However, our analysis of the system suggested that it is not quite that easy. Sure, there are three general steps involved in using the system, but implementation of those steps requires the user to do 52 substeps! The first column of the table on pages 8–9 lists all the steps required to test one's blood using a typical blood glucose meter. Setting up the meter requires 6 steps, checking the system requires 22 steps, and testing of the blood glucose level requires 24 steps. This level of complexity is not unique to one particular meter; we conducted a task analysis on another commonly used meter and found 61 substeps.

When people are told that a system is trivially easy to use but have difficulties with it, they tend to blame themselves. They may be too embarrassed to ask for assistance, stop using the system altogether, or continue to use it without realizing they're using it incorrectly. Additional evidence that blood glucose meters are *not* trivially easy to use comes from a study conducted to assess the accuracy of the blood glucose readings obtained by diabetics using blood glucose meters (Colagiuri, Colagiuri, Jones, & Moses, 1990). Colagiuri et al. tracked 90 patients using two different meters for one month. Participants were asked to test previously measured solutions. The results showed that 62% of the patients made at least one error that was classified as "clinically significant," meaning that the patient either would have taken a medically inappropriate action or failed to take a medically appropriate action based on the incorrect reading.

According to the error classification conducted by Colagiuri et al., the most frequent cause of the error was a "faulty technique" on the part of the user. In these researchers' words, "the most commonly encountered error arose from the patient not adhering to the

Contrary to manufacturers' claims about ease of use, real users report a number of problems with complex devices at home.

specific instructions of the manufacturer. . . . [I]n most cases errors resulted from a general lack of care on the part of the patient in complying with the manufacturer's instructions" (p. 803).

However, we would be wise to heed the counsel of experts in the field of human error:

> To assign blame to an individual who makes an error is no assurance that the same error will not be made again by a different person. (Van Cott, 1994, p. 61)
>
> People of good intention, skilled and experienced, may nonetheless be forced to commit errors by the way in which the design of their environment calls forth their behavior. (Moray, 1994, p. 67)

In other words, it is not appropriate to blame the user for making an error when the root cause of the error may really be the design of the system itself or the type of instructions provided to users.

Uncovering Sources of Errors

How do we determine the actual sources of errors in a particular system? The field of human factors/ergonomics has much to offer in this regard. The strength of an HF/E approach is that it can be *predictive* in helping to anticipate errors, as well as *prescriptive* in motivating design and instructional development. Proper HF/E analysis can reveal when the fault might lie with the design of the system or instruction rather than with the user. Moreover, human factors analysis can reveal ways to improve design and instructions to minimize error.

Task Analysis

The path to understanding the source of errors in a task begins with an in-depth understanding of what a person has to do when performing that task (see Figure 1, page 10). We conducted a task analysis of a sample blood glucose meter to help us understand the errors that may be made when using a typical meter (see the table on the following pages). The meter we analyzed is readily available at major pharmacies and is representative of commonly used systems. It requires three calibration procedures. First, each time a new box of test strips is used, a code on the meter must be set to match a code provided on the test strip vial. Second, the meter must be calibrated periodically by using a special check strip. Third, to ensure that the meter is providing correct glucose readings, the patient is instructed to perform regular tests using a glucose control solution.

Each task was defined in terms of the information required by a user to complete each task (task/knowledge requirements), the feedback provided by the system, and the potential problems that might arise if the task were not carried out properly (see the table). Testing blood glucose levels using a meter requires substantial procedural, step-by-step knowledge. The task analysis demonstrated that many of the tasks require knowledge of the correct procedure and location and function of the control button: to successfully complete each step. This particular meter has two control buttons, whereas other meters we examined had three

Figure 1. A blood glucose meter and associated components.

TASK ANALYSIS FOR A STANDARD BLOOD GLUCOSE METER

Task No.	Task	Task/Knowledge Requirements	Feedback	Potential Problems
1.0	**Set up the meter**			
1.1	Select the display language			
1.1.1	Press and hold the C button	Location of C button	Tactile (feel button action)	Cannot locate button
1.1.2	Press and release the On/Off button	Location of On/Off button	Meter beeps when turned on; meter displays last reading	Cannot locate button Fail to release button
1.1.3	Release the C button	Location of C button	Tactile (feel button action)	Cannot locate button
1.2	Code the meter			
1.2.1	Turn on the meter	Location of On/Off button	Meter beeps when turned on; meter displays last reading	Cannot locate button
1.2.2	Compare the code numbers on the meter and test strip package	Location of correct code number	None	Cannot find correct code number on package
1.2.3	Press the C button until the codes match	Location of the C button	Tactile (feel button action); code changes on display	Enter incorrect code number
2.0	**Check the system**			
2.1	Perform a check strip test			
2.1.1	Make sure the test area is clean	Location of test area	None	Test area not cleaned
2.1.2	Turn the meter on	Location of On/Off button	Meter beeps when turned on; meter displays last reading	Cannot locate button
2.1.3	Wait for meter to say "Insert Strip"	Location of display	Meter displays instructions	Does not observe instructions on display; inserts strip too early
2.1.4	Slide side 1 of the check strip into the test strip holder	Location of the test strip holder; proper orientation of check strip	Meter displays "Apply Sample" when it detects something	Insert check strip incorrectly; insert something other than a check strip
2.1.5	Wait for the meter to say "Apply Sample"	Location of the display; correct procedure	Meter displays instructions	Does not remove check strip from holder; applies blood or control solution; does not wait for instructions
2.1.6	Slide the check strip out of the test strip holder	Correct procedure	Meter displays "Insert Side 2" when strip is removed	Does not remove check strip
2.1.7	Wait for the meter to say "Insert Side 2"	Location of the display; correct procedure	Meter displays instructions	Does not wait for the instructions
2.1.8	Slide side 2 of the check strip into the test strip holder	Location of test strip holder	Meter counts down when it detects something	Insert check strip incorrectly; insert something other than a check strip
2.1.9	Wait for the meter to count down from 4 to 0	Location of the display; correct procedure	Meter displays count and beeps when finished	Does not wait for meter to count down
2.1.10	Observe reading on the meter	Location of the display; indication of satisfactory test	Meter displays calibration result	Fail to observe result and verify it is satisfactory
2.2	Perform a glucose control solution test			
2.2.1	Check that the correct glucose control solution is being used	Correct solution type	None	Incorrect control solution used
2.2.2	Check the expiration date on the control solution vial	Location of expiration date	None	Expired control solution used
2.2.3	Shake the control solution vial vigorously	Correct procedure	Tactile (feel solution mix in bottle)	Vial not shaken; control solution not properly mixed
2.2.4	Turn on the meter	Location of On/Off button	Meter beeps when turned on; meter displays last reading	Cannot locate button
2.2.5	Remove a test strip from the package	Location of packet	Tactile	Unable to open packet
2.2.6	Wait for meter to say "Insert Strip"	Location of display	Meter displays instructions	Does not observe instructions on display; inserts strip too early
2.2.7	Insert test strip into the test strip holder	Location of the test strip holder; proper orientation of test strip	Meter displays "Apply Sample" when it detects something	Insert test strip incorrectly

2.2.8	Wait for the meter to say "Apply Sample"	Location of the display; correct procedure	Meter displays instructions	Does not wait for instructions
2.2.9	Apply glucose control solution to test strip	Correct procedure; where to apply control solution	Meter beeps when it detects moisture	Incorrect solution used; solution applied to wrong location
2.2.10	Wait for the meter to count down from 45 to 0	Location of the display; correct procedure	Meter displays count and beeps when finished	Does not wait for the meter to count down
2.2.11	Read the control solution test results	Location of the display; indication of test results	Meter displays test result	Fail to note test result
2.2.12	Compare the reading on the meter with the range on the test strip package	Location of the correct range on package; correct procedure	None	Fail to observe result and verify it is in the correct range
3.0	**Test your blood**			
3.1	Gather the correct materials (meter, test strips, lancing device, lancet)	What items are required; location of required items	None	Forget an item; gather incorrect item
3.2	Check to be sure the test strip area is clean	Location of test area	None	Test area not cleaned
3.3	Check the expiration date on the test strip package	Location of expiration date	None	Fail to check expiration date
3.4	Turn on the meter	Location of On/Off button	Meter beeps when turned on; meter displays last reading	Cannot locate button
3.5	Remove a test strip from the package	Location of packet	None	Unable to open packet
3.6	Wait for meter to say "Insert Strip"	Location of display	Meter displays instructions	Does not observe instructions on display; inserts strip too early
3.7	Insert test strip into the test strip holder	Location of the test strip holder; proper orientation of test strip	Meter displays "Apply Sample" when it detects something	Insert test strip incorrectly
3.8	Wait for the meter to say "Apply Sample"	Location of the display; correct procedure	Meter displays instructions	Does not wait for instructions
3.9	Get a drop of blood			
3.9.1	Remove the lancing device cap	Correct procedure	Tactile	Lancing device cap not removed
3.9.2	Insert a sterile lancet into the lancet holder	How to insert lancet	Tactile	Lancet inserted incorrectly
3.9.3	Twist off the lancet protective cap	How to remove protective cap	Tactile	Protective cap not removed
3.9.4	Replace the lancing device cap	How to replace lancing device cap	Tactile	Lancing device cap not replaced or replaced incorrectly
3.9.5	Cock the lancing device	How to cock the lancing device	Lancing device clicks when cocked	Lancing device not cocked
3.9.6	Wash your hands	Correct procedure	None	Hands not washed; possible infection
3.9.7	Hang your arm at your side for 10-15 seconds	Correct procedure; proper length of time	None	Don't hang arm at side; unable to get good blood flow to fingers
3.9.8	Hold the lancing device against the side of a finger	Correct location to prick finger	Tactile	Lancing device not held against finger; unable to get blood
3.9.9	Press the release button	Location of release button	Tactile (feel finger pricked)	Unable to prick finger
3.9.10	Squeeze the finger to obtain a large, hanging drop of blood	Correct procedure	Blood produced	Not enough blood produced; blood is smeared rather than hanging
3.10	Apply blood sample to test strip	Proper location to apply blood sample	Meter beeps once when moisture detected	Blood not placed on proper location; not enough blood applied for a reading
3.11	Wait for the meter to count down from 45 to 0	Location of the display; correct procedure	Meter displays count and beeps when finished	Does not wait for the meter to count down
3.12	Read the blood glucose test results	Location of the display; indication of test results	Meter displays test result	Fail to note test result
3.13	Turn the meter off	Location of the On/Off button	Display goes blank	Fail to turn meter off
3.14	Record your test result	Remember test result	None	Record wrong test result; fail to record result
3.15	Remove the lancet from the lancing device and discard	Correct procedure	None	Unable to remove lancet; discard lancet in unsafe location

buttons: to change the time on the meter, recall readings stored in memory, and perform calibration procedures. In all meters reviewed, the tasks were sequential and required a great deal of procedural knowledge to obtain accurate blood glucose levels.

Whether the system provided information for each step of the process tended to vary. In most cases, feedback from the meter was not informative. The meter provides the same prompts regardless of the task being done (a calibration procedure or actual glucose testing). Sometimes the feedback is misleading. When testing a drop of blood using a normal test strip, the user sees the message "Apply Sample" on the meter, and this feedback is useful. However, if the user is calibrating the meter using a check strip and "Apply Sample" appears, he or she is supposed to slide the check strip out of the test strip holder. In this circumstance, the feedback message is misleading and potentially error-inducing.

were poorly designed, or the users never received any instructions to start with.

Home medical devices often have step-by-step instructional manuals. The meter we examined came with three instructional pamphlets: a user's manual, instructions included with the test strips, and instructions for a lancing device, which holds the lancet (i.e., sterile needle) used to prick the finger to obtain a drop of blood for testing. The meter also included an instructional video. We analyzed the content of the text materials and the instructional video to determine whether these materials might contribute to user error.

A global measure of readability of text material is the grade level and percentage of the population that could read and understand it. Standard writing equates to a seventh- or eighth-grade level, but the recommended level of writing for general information is sixth grade (McLaughlin, 1969).

Sure, there are three general steps involved in using the system, but implementation of those steps requires the user to do 52 substeps!

A variety of problems might occur when testing blood glucose levels. In some instances, the problems may not affect the test result. For example, if the user forgets to verify whether the code number on the meter matches the number on the test strip vial, there are no consequences. But sometimes errors may affect the blood glucose reading. For instance, the code on the meter may differ from that on the test strip vial. The user may neglect to perform regular check strip or control solution calibration tests. Or the user may not wait for the prompts on the meter and may be unable to obtain a test result at all. The most critical errors are likely to be those that result in an incorrect glucose reading, which could then lead to the incorrect insulin dosage or erroneous adjustments in other treatments.

Perhaps the most striking aspect of the task analysis is the complexity of this supposedly "simple" medical device. With 52 total steps for calibrating, testing, and using the meter, there are many opportunities for error. The sequential nature of the task itself might contribute to problems because an error early in the process carries through (e.g., inserting the strip incorrectly). Given the complexity of the task, it is crucial that users receive the necessary instructions to be able to use the system safely and effectively.

Instruction Analysis

Another mechanism for understanding the potential sources of errors is to review the type(s) of instruction that the user receives. Perhaps the instructions are too complex for the user to understand, or the instructions

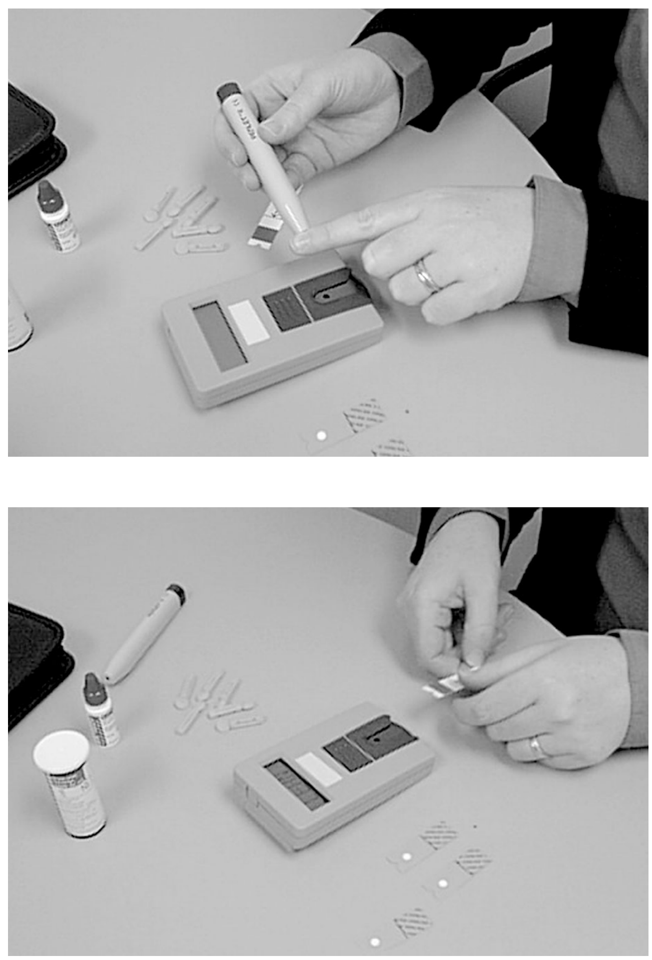

Figure 2. Top: Obtaining a blood sample; bottom: applying sample to a test strip. The strip is then inserted into the meter.

We analyzed the instructions that were provided with the meter for reading level using the Flesch-Kincaid Grade Level analysis. The user's manual was written at an eighth-grade level and would be readable by about 58% of the U.S. population. The instructions for using the lancing device were written at a sixth-grade level and considered readable by 72% of the population. However, the instructions for the test strips were written at a more advanced level – ninth to tenth grade – which is readable by only 51% of the population. In the United States, about 23 million people aged 25 and older would not be able to read and understand materials written at this grade level (U.S. Census Bureau, 1997). Therefore, we determined, through the reading level analysis, that the instructions would not be understood by segments of the intended user population.

In our analyses, we also considered the content of the instructional video provided with the meter. Calculations of text complexity based on a transcription of the video instructions yielded a rating of about the seventh-grade level, comprehensible by 72% of the population. This indicates that the vocabulary may be more advanced than desired to ensure comprehension by the general population.

Analysis of the video is instructive. It begins with an introduction and advertisement recommending the product. This is followed by a testimonial from a pharmacist who recommends the meter and then a brief overview of the major steps required to perform a blood glucose test. Following the overview, each of the main steps (procedures for calibration, testing blood glucose levels, and cleaning/maintaining the meter) is described by a different actor. The pharmacist concludes the video by instructing users to refer to the user's manual for further instructions. The manufacturer's toll-free customer support number is then provided.

On the surface, the video may seem useful for training; it provides demonstrations of each component, and every critical step is described and shown, with a close-up view of the meter and other equipment as someone performs the step. In some instances, editing techniques, such as a grayed-out screen with the item of interest highlighted, are used to focus attention on the pertinent element in the scene. However, our instructional analysis revealed some potential problems.

First, the main steps are never reiterated or reviewed in the video. Only when the pharmacist provided an overview of the basic steps to test blood glucose levels were the instructions previewed or summarized. The video also switches back and forth between showing the actor in the segment and a close-up view of the meter or the relevant portion of the meter (i.e., the display or the test strip holder). As a result, aspects of the procedure may be missed.

It is not appropriate to blame the user for making an error when the root cause of the error may really be the design of the system itself.

Usability Analysis

To assess whether viewing the video instructions would provide sufficient training for someone to perform the tasks, we tested a sample of individuals on several of the component tasks. We focused on the three calibration tasks: set the code, perform a check strip test, and perform a glucose control solution test. Six participants – four older adults (mean age 70 years) and two younger adults (mean age 21 years) – watched the portion of the video relevant to the three calibration tasks and then performed each calibration test, one at a time.

Only two of the participants (one younger, one older) were able to set the code on the meter. The remaining four skipped the first calibration altogether and tried to use a check strip test. One of these participants (a younger adult) realized that he had not set the code and later performed this calibration. The other three (all older) never checked or changed the code, which is important in ensuring that the reading is accurate for the particular set of test strips.

The second task was to perform a check strip test. Four people (two younger, two older) successfully completed this test. One older adult was unable to perform the task initially, but when prompted to start over, she was able to complete it successfully. The remaining older adult performed the test by happenstance when trying to do something else.

The third task was to perform a glucose control solution test. Four participants (two younger, two older) were able to obtain a control solution reading. One older adult received an error on her first try and was not able to complete it a second time. The remaining older adult was not able to get a reading because he failed to use a test strip on his first try, and, even when prompted, he could not complete the test. It is important to note that no one remembered to check the type of control solution or to check the expiration date on the solution, even though these activities were described on the videotape.

Participants had some difficulties performing the three calibration tests that represent only a small subset of the tasks required to use a blood glucose meter successfully (see the table on pages 8–9). If they had watched

the entire video and then been asked to perform all the tasks, we suspect they would have had even more difficulties. Note also that the older adults tended to have more difficulties, but performance was not perfect for the young adults either. In sum, the video instructions may *appear* to be an organized and straightforward means of training someone to use a blood glucose meter, but our empirical evidence suggests otherwise.

The task analysis presented in the table illustrates the complexity involved in using a blood glucose meter. Clearly, it is not a simple three-step process. There is a lot to learn, and the multitude of sequential steps leads to the possibility of a cascade of errors caused by both design and training issues. Proper design of the device, coupled with clear and easy-to-follow instructions, is critical. In addition, the design of the system and of the instructional materials must meet the needs of all potential users.

meter is not trivially easy to use and requires some experience to use it comfortably.

More than 70% reported having problems using the system when first learning to use it. They reported problems such as remembering the steps, setting up the meter, calibrating the meter, using the lancet, getting a blood sample, and reading the display.

Perhaps more telling was the finding that survey respondents had used an average of 2.5 different brands of meters (range = 1-7, mode = 3). Dissatisfaction with particular blood glucose meters led them to try new meters, although there were also cost reasons for switching. Reasons for changing meters were as follows: 40% wanted a meter that was easier to use, 25% sought different features, 15% were seeking a lower-cost alternative, and 20% had received recommendations from others.

When asked how they had first learned to use a blood glucose meter, 49% of respondents said they learned, at least in part, from the user's manual. Most users learned to use these systems on their own and likely believe that they are performing the task adequately. However, self-instruction based on manufacturer manuals may be insufficient for accurate performance with a blood glucose meter. Ward, Haas, and Beard (1985) found that after 30 minutes of self-instruction and practice, participants made errors 20% to 40% of the time.

Participants had some difficulties performing the three calibration tests that represent only a small subset of the tasks required to use a blood glucose meter successfully.

The next most common way for respondents to learn to use a blood glucose meter was from a nurse, doctor, or health professional (30%). However, these individuals may not have the time to devote to training users; for some meters, participants in another study needed an average of 23.9 (±4.5) minutes to learn to use the system, and they continued to make errors even after this training (Tomky & Clarke, 1990).

The remaining respondents in our survey learned to use their meter from other materials provided by the manufacturer (8%), trial and error or past experience (8%), or a friend or family member (8%). (Note that several people provided more than one answer to this question, and the percentages represent the percentage of the total number of responses.)

Participants' Self-Reports

Another valuable tool in the HF/E arsenal is to interview the users of a particular system. We conducted a survey of people who have experience using blood glucose meters. The survey included questions concerning demographic information (e.g., age, education, sex, race), blood glucose meter usage patterns (e.g., frequency, assistance, length of experience), difficulties using the system (e.g., remembering steps, reading the display), and open-ended questions about likes, dislikes, and suggestions for improvements.

Surveys were completed by 26 individuals with a mean age of 59 years (11 women, 15 men; 4 African-American, 21 Caucasian, 1 mixed Anglo-Hispanic). The average number of years of formal education was 15 or more years, and all respondents reported having at least some college education. All were diabetics who used a blood glucose meter, typically at least once per day, and had been using a meter for an average of seven years. Although this sample is relatively small, the data are suggestive of the range of problems potentially encountered, and the anecdotal comments are of interest.

Respondents were asked how many times they had to use their blood glucose meter before they felt completely comfortable with it; 32% said 1-2 times, 40% said 3-4 times, 20% said 5-10 times, and 8% said they had to use the meter more than 10 times in order to feel comfortable. This pattern shows that the blood glucose

Toward Solutions for Reducing Error

Based on prior studies, our task analysis, reported problems from current users, and observed difficulties calibrating a blood glucose meter, users clearly have difficulties using these devices, and there are many sources

of error. If they are unable to use meters properly, patients are unable to adjust treatment of their diabetes. There are two areas where improvements can reduce errors: the design of the system and the design of instructional materials that teach people to use these devices.

System Design

Our survey data provide some directions for system redesign. We asked respondents, "If you could design a new and improved blood glucose meter, what things would you change?" Their answers covered these broad categories:

1. *Modify the strips:* make them longer; standardize the test strips; reduce the price; make the area on the strip that receives blood larger; automatically indicate an insufficient amount of blood and allow an addition of blood to the same strip; change the packaging of strips.
2. *Modify the meter:* reduce the amount of programming required; make it simple and easy to use; make steps more accessible; make it smaller.
3. *Modify the features:* add memory, date, and time; shorten processing time; increase memory; include attachable clamp so it can be worn like a beeper.
4. *Modify the blood-sampling procedure:* require a smaller amount of blood; develop better ways to get a drop of blood.
5. *Modify major systems:* eliminate the need for calibration; make it self-contained; design a blood glucose meter that can communicate directly with an insulin pump; make it lighter; build a lancet device within the system; develop a noninvasive unit.

Recent design improvements on blood glucose meters could address some of the aforementioned broad categories. For example, the category "modify the blood-sampling procedure" may have been addressed with recent blood glucose sampling advances. However, other design issues remain, and the new systems may themselves have unforeseen problems that require human factors/ergonomics analysis.

One design improvement evident from our task analysis (see the table on pages 8–9) is the need for appropriate, task-specific feedback. For example, the meter should be able to recognize a check strip used for calibration versus a test strip used for glucose testing. After recognizing the test strip, the meter should provide the feedback that is appropriate to the task the user is performing. In addition, given the sequential nature of the tasks involved, meters that provide prompts for the proper sequence of the tasks might help to reduce errors (see Gardner-Bonneau & Gosbee, 1997, for additional design recommendations).

It is important to consider the benefits of ostensible design improvements. For example, early meters required that excess blood be wiped off the reagent strip. Newer, "no-wipe" technology eliminated this aspect of the procedure. However, eliminating this step did not improve the blood sample because errors still occurred if the test strip was not sufficiently covered with the sample (Kelly, Callan, & Meadows, 1991). So although the improved technology may have minimized certain kinds of errors, it did not solve the problem of obtaining an adequate blood sample.

It is also important to consider the constraints of design recommendations. Design involves trade-offs. For example, users may want a portable blood glucose meter that is small enough to carry around, but when the system gets too small, it becomes difficult to work with, and the display cannot be easily read, among other things. The critical point is that design ideas must be tested with the target user population.

> Most users learned to use these systems on their own and likely believe that they are performing the task adequately.

Instructional Design

Nearly 50% of the respondents in our survey said the user's manual was a primary source of instructions. Given this reliance on training materials, it is critically important that such materials be well designed. Ideally, the development of training programs and instructional materials should follow Instructional System Design models (for a review, see Wickens, Gordon, & Liu, 1998). Such models include an analysis to determine the specific training needs for the system. A task analysis such as we conducted would be included, as well as an analysis of the characteristics of the trainees (e.g., education, perceptual and cognitive abilities) and of the resources available (e.g., access to a videocassette recorder for video-based training).

Design and development of the training materials involves selecting the method of training (e.g., step-by-step instructions, modeling) and the media in which the training will be administered (e.g., text, video). For both written and spoken instructions, particular care should be taken in the following areas:

- Ensure that readability levels are appropriate for the intended user population.
- Keep the vocabulary simple and explicit; avoid jargon.

- Minimize the need for readers and listeners to draw inferences.
- Use numbered steps to describe procedures.
- Emphasize critical components or warnings.
- Provide advance organizers, such as an initial overview or outline of the information to be presented, to help users conceptualize the information.
- Describe the steps in the same order in which they will be performed.
- Provide redundancy of information either through multiple modes (text and figures, written and spoken) or through the repetition of critical information.

Training materials should be developed iteratively; in other words, materials are tested with typical users of the systems, benefits of training are assessed, and the materials are refined as needed. In the case of training and instruction for a blood glucose meter, testing must include diabetics who represent the range of education, perceptual function, and cognitive ability levels of the typical diabetic who will be expected to use the system.

The last phase of instructional system design is program evaluation: Is the training system effective? Do the training materials enable trainees to use the system safely and effectively? The evaluation should be based on users across time, tracking errors they make, determining the potential need for refresher training (e.g., do they lapse into bad habits, forgetting critical steps such as calibrating the meter), and so on.

Conclusion

The possibility for design-induced human error associated with blood glucose meters is prevalent, which argues strongly for human factors intervention. Our analysis focused on a single device, but a blood glucose meter is representative of a class of medical devices. Our purpose was to demonstrate the need for human factors/ergonomics intervention early in the design process of medical devices, especially those designed for home use.

The blood glucose meters we reviewed were designed specifically for patient use. The HF/E concerns may be even more serious for classes of devices that were initially designed for hospital use but are now being used in the home, such as ventilators and infusion pumps (Klatzky & Ayoub, 1995). We caution development teams to be aware of the potential for design-induced errors, to make every effort to design out those errors, and then to develop adequate training and instruction protocols for the users of the device.

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